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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,934	11/15/2001	Zoltan Nagy	GPCG-P01-003	8886

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/001,934	NAGY ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *22-25,28,29,67,81-83,86,87,117,118 and 124-129* is/are allowed.

6)☐ Claim(s) *7-21,26,27,33-37,43,55,56,59-63,71-79,84,85,92-95 and 120-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 7-29,33-37,43,55,56,59-63,67,71-79,81-87,92-95,117,118 and 120-129.

DETAILED ACTION

Claims 7-29, 33-37, 43, 55, 56, 59-63, 67, 71-79, 81-87, 92-95, 117, 118, 120-129 are pending and under consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 26, 27, 33-37, 43, 55, 56, 59-63, 71-79, 84, 85, 92-95, 120-123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is vague and indefinite in the recitation of "the VH CDR3 sequence" without an indication if the following sequence data was part of the antibody combination of HuCAL VH2 and HuCAL V lambda 1, or the sequence data is a partial characteristic of the antibody which competes with the aforesaid antibody.

Claim 27 is vague and indefinite because it is unclear if "said antibody" refers to the antibody including a combination of HuCAL VH2 and HuCAL Vlambda, or if "said antibody" refers to the antibody which competes for binding to the aforesaid antibody.

Claim 84 is vague and indefinite because it is unclear if the VH CDR3 sequence is further modifying the antibody including a combination of HuCAL VH2 and HuCAL .

Claim 85 is vague and indefinite because it is unclear if "said antibody" refers to the antibody including a combination of HuCAL VH2 and HuCAL Vlambda, or if "said antibody" refers to the antibody which competes for binding to the aforesaid antibody.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 20, 21, 26, 35, 36, 55, 59, 61, 71, 73, 78, 79 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Ge et al (Human Immunology, 1995, Vol. 42, pp. 27-34, reference of the IDS filed Nov 23, 2007).

Claim 26 is drawn to a composition including a polypeptide comprising an antibody-based antigen-binding domain of human composition with binding specificity for HLA-DR antigen expressed on the surface of a human cell, wherein treating cells expressing said antigen with a multivalent polypeptide having two or more of said antigen-binding domains leads to killing of said cells, wherein said antigen-binding domains causes or leads to killing of said cells, wherein said antigen-binding domain competes for binding to antigen with an antibody including a combination of HuCAL VH2 and HuCAL V lambda2, wherein VHCDR3 sequence is taken from the consensus CDR3 sequence of SEQ ID NO:1 and the VL CDR3 sequence is taken from the consensus of CDR3. The claim does not specify that the antibody which competes with the binding of the antibody including a combination of HuCAL VH2 and HuCAL V lambda2 comprises the recited VH CDR3 or VL CDR3, therefore the limitation of comprising the recited VH CDR3 or VL CDR3 is applied to the antibody including a combination of HuCAL VH2 and HU CAL Vlambda.

Claim 84 is drawn to a composition including a polypeptide comprising at least one antibody-based antigen binding domains with a binding specificity for human HLA-DR antigen with a Kd of 1uM or less, wherein treating cells expressing said antigen with said polypeptide causes or leads to suppression of n immune response, wherein said antigen-binding domain competes for antigen binding with an antibody including a combination of HuCAL VH2 and HuCAL V lambda2, wherein VHCDR3 sequence is taken from the consensus CDR3 sequence of SEQ ID NO:1 and the VL CDR3 sequence is taken from the consensus of CDR3. The claim does not specify that the antibody which competes with the binding of the antibody including a combination of HuCAL VH2 and HuCAL V lambda2 comprises the recited VH CDR3 or VL CDR3, therefore the limitation of comprising the recited VH CDR3 or VL CDR3 is applied to the antibody including a combination of HuCAL VH2 and HU CAL Vlambda1.

Ge et al disclose the human antibody Trj11 which binds to HLA-DR on lymphoid cells, wherein the epitope bound by the Trj11 antibody is located in the DR chain. Ge et al disclose that the Trj11 antibody binds to one or more of the DR4 subtypes in claims 20 and 78 and at least

5 different HLA-DR types (page 29, under "Specificity of mAb Trj11). Ge et al disclose that Trj11 binds to the B-chain of HLA-DR on (page 29, second column, last sentence)thus fulfilling the limitation of claims 18 and 71. Ge et al disclose that the Trj11 antibody if a IgM antibody, thus fulfilling the limitations of claim 35 as well as claim 36 because an IgM antibody is a multivalent composition. The Trj11 antibody fulfills the limitations of claim 55 drawn to a diagnostic composition because claim 55 does not comprise any limitation that would exclude the form of the antibody used by Ge et al. Ge et al disclose that the "Microlymphocytotoxicity assay" was used in conjunction with the Trj11 antibody which meets the limitation of claim 59 drawn to a kit comprising a composition of claims 22-29 and a means to measure the degree of killing or immunosupression of said cells. It is noted that the intended use of identifying patient that can be treated with a composition of any of claims 22-29 is not given patentable weight. Ge et al disclose the Trj11 antibody used in conjunction with a detectable moiety and reagents and/or solutions to effect and/or detect binding of the composition to an antigen (page 28-29, under the heading of "Fluorescence cytometry").

The reference does not specifically disclose all the properties of the instant claimed antibodies which bind to HLA-DR, however, the claimed antibodies appears to be the same as the prior art therapeutic agents in terms of binding specificities and cross reactivities, absent a showing of unobvious differences. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 22-25, 28, 29, 67, 81-83, 86, 87, 117, 118, 124-129 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643